IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

UNITED STATES OF AMERICA and THE STATE OF NORTH CAROLINA *ex rel.* LEE M. MANDEL, MD, FACS, and ERIN CRAIG,	)	
Plaintiffs,	)	**No. 17-CV-925**
v.	)	**JURY TRIAL DEMANDED**
ANITA LOUISE JACKSON, MD and GREATER CAROLINA EAR, NOSE & THROAT, P.A.,	)	
Defendants.	)	

THE UNITED STATES' AND THE STATE OF NORTH CAROLINA'S COMPLAINT IN INTERVENTION

For their Complaint in Intervention, the United States of America, by and through Sandra J. Hairston, the Acting United States Attorney for the Middle District of North Carolina, and the State of North Carolina, by and through Joshua H. Stein, Attorney General for the State of North Carolina, allege as follows:

INTRODUCTION

1. The United States of America and the State of North Carolina (collectively referred to as "the Governments") bring this action against Defendants pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, and the North Carolina False Claims Act (NCFCA), N.C.G.S. §1-605 *et seq*., seeking treble damages and civil penalties, and under common law and equitable theories of recovery.

2. As described below, Defendant Greater Carolina Ear, Nose, and Throat, P.A. (GCENT) and Defendant Anita Louise Jackson, M.D. (Dr. Jackson) created a money-making scheme by billing to Medicare and Medicaid vast quantities of balloon sinuplasty procedures that were either not performed or were performed regardless of whether the procedures were reasonable and necessary for the treatment of any individual patient.

3. As GCENT and Dr. Jackson were aware, Medicare generally only covers procedures that are reasonable and necessary for the treatment of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for each procedure, for each patient, must be individually assessed and documented in the patient's medical chart. 42 U.S.C. § 1395l(e); *see also* 42 U.S.C. § 1320c-5(a). Defendants' patient charts were woefully deficient of documentation to substantiate that the procedure had been performed or that the patient had a medical need for the procedure. Similarly, Medicaid providers may only submit claims for reimbursement that are medically necessary under the North Carolina Medicaid program.

4. At Dr. Jackson's direction, GCENT staff created advertisements to bring in patients to receive a balloon sinuplasty procedure, regardless of whether such procedure was indicated for each patient. Contrary to industry standards, Dr. Jackson would often perform the procedure on a patient's first visit to the office and/or without a computed tomography (CT) scan, in addition to reusing the single-use balloon dilation device needed to perform the procedure. Dr. Jackson frequently performed repeat balloon sinuplasty surgeries, despite little medical evidence that repeat surgery is effective, without regard to

medical necessity. Nonetheless, Dr. Jackson and GCENT billed Medicare, Medicaid, and other Federal health care programs for the balloon sinuplasty procedures.

5. Through these and other practices, from at least September 2012 through November 2018 ("the relevant time period"), Defendants knowingly submitted and caused to be submitted millions of dollars in false claims to Federal health care programs, by billing or causing to be billed to Federal health care programs claims for balloon sinuplasty procedures that were either not performed or not medically reasonable and necessary, in violation of the FCA.

JURISDICTION

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345. The Court has supplemental jurisdiction over the common law and equitable causes of action under 28 U.S.C. § 1367(a). Further, this Court has supplemental jurisdiction over the claims of the State of North Carolina pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

7. This Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because each Defendant resides and/or transacts business in the Middle District of North Carolina.

8. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b), because Defendants transact business in this District, and a substantial part of the events giving rise to this action occurred in this District.

PARTIES

9. Plaintiff, the United States of America brings this action on behalf of the United States Department of Health and Human Services (HHS), which, through the Centers for Medicare & Medicaid Services (CMS), administers Medicare and jointly funds Medicaid with each state that chooses to participate in that program. Operating within broad federal rules and guidelines, each state administers its own Medicaid program and provides health care benefits for certain groups, primarily low-income individuals and people with disabilities.

10. Plaintiff, the State of North Carolina brings this action on behalf of the North Carolina Department of Health and Human Services, Division of Health Benefits (NCDHB).[1] NCDHB administers the Medicaid program in North Carolina.

11. Defendant Dr. Jackson is a resident of Wake County, North Carolina, and a physician licensed to practice medicine in North Carolina from at least 1997. During the relevant time period, she was GCENT's owner and operator.

12. Defendant GCENT is a Professional Association authorized and existing under the laws of the State of North Carolina, with its principal place of business in Lumberton, North Carolina. GCENT also currently operates an office in Rockingham, North Carolina. During the relevant time period, GCENT additionally operated offices in Raleigh and Garner, North Carolina. Defendant GCENT was created in 1997, suspended

[1] The Division of Medical Assistance (NCDMA) previously administered the Medicaid program in North Carolina.

by the North Carolina Secretary of State in 2005, 2012, and 2019, and reinstated in 2007 and 2012.

13. During the relevant time period, Dr. Jackson and GCENT participated in and submitted claims for reimbursements to Federal health care programs, including Medicare and Medicaid.

LEGAL AND REGULATORY BACKGROUND

I. The False Claims Act

14. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A) [or] (B) …

is liable to the United States for three times the amount of damages which the Government sustains, plus a civil penalty per violation. 31 U.S.C. § 3729(a). For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amounts range from a minimum of $5,500 to a maximum of $11,000. *See* 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, *47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of $11,665 to a maximum of $23,331. 28 C.F.R. § 85.5.

15. For purposes of the FCA,

> the terms "knowing" and "knowingly" (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in

> reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. . . .

31 U.S.C. § 3729(b)(1).

16. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

17. The North Carolina FCA provides, in pertinent part, that any person who:

> (a)(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
> (a)(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (a)(3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7); … [or]
> (a)(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State …

shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000), as may be adjusted by Section 5 of the Federal Civil Penalties Inflation Adjustment Act of 1990, P.L. 101-410, as amended, for each violation.

18. For purposes of the NCFCA,

> "Knowing" and "knowingly."--Whenever a person, with respect to information, does any of the following:

> a. Has actual knowledge of the information.
> b. Acts in deliberate ignorance of the truth or falsity of the information.
> c. Acts in reckless disregard of the truth or falsity of the information.
> Proof of specific intent to defraud is not required…

N.C.G.S. §1-606(4).

19. The NCFCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." N.C.G.S. §1-606(5).

II. The Medicare Program

20. In 1965, Congress enacted Title XVIII of the Social Security Act (Act), known as the Medicare program (Medicare), to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395, *et seq*. HHS is responsible for overseeing Medicare and entrusts CMS, one of its components, to administer the program.

21. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Individuals who are insured under Medicare are called Medicare "beneficiaries."

22. Medicare consists of four parts: A, B, C, and D. Part B covers outpatient care, including physician services and ancillary services, such as outpatient procedures, furnished by physicians and other providers and suppliers.[2] 42 U.S.C. § 1395k.

[2] In the relevant regulations, physicians and other practitioners are generally referred to as "suppliers" in Medicare, rather than "providers." *See* 42 C.F.R. § 400.202. This Complaint nonetheless uses the common term "provider" to refer to individual practitioners.

23. Medicare Part B generally only covers services, including outpatient surgical procedures, which are reasonable and necessary for the diagnosis or treatment of an illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).

24. The Secretary of HHS (Secretary) has authority to determine the meaning of "reasonable and necessary" under section 1862(a)(1)(A) of the Act and whether a particular medical item or service is "reasonable and necessary" under the same section of the Act. *See* 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). Typically, the Secretary accomplishes both functions via formal CMS regulations and sub-regulatory guidance.

25. CMS uses a publicly accessible online manual to help administer its healthcare programs, including Medicare. *See generally*, CMS Internet-Only Manuals (IOMs), *available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html (last visited September 7, 2021) (hereinafter "CMS Manuals"). These manuals—used by CMS program components, Medicare contractors, other CMS partners, and accessible to Medicare providers—offers day-to-day operating instructions, policies, and procedures based on statutes, regulations, guidelines, models, and directives.

26. At all times relevant to this complaint, CMS contracted with private contractors, referred to as Medicare Administrative Contractors (MACs) (formerly known as fiscal intermediaries under Part A and carriers under Part B), to act as agents to perform various administrative functions on CMS' behalf, including adjudicating claims submitted by health care providers who are enrolled in Medicare under Parts A and/or B. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104, 421.200, 421.400, 421.401, 421.404.

27. During the relevant time period of this Complaint, Palmetto GBA was the MAC responsible for processing Medicare Part B claims in North Carolina.

28. As outlined in CMS' Medicare Program Integrity Manual, where no formal guidance from CMS or MACs otherwise exists, a service is considered reasonable and necessary, inter alia, if it was "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed member[.]" CMS Manual, Pub. 100-08, Ch. 3, Sec. 3.6.2.2; *see also* 42 C.F.R. § 405.201(b).

29. In addition to MACs, CMS contracts with other private contractors, known as Unified Program Integrity Contractors (UPICs)[3], to perform program integrity functions for Medicare, including medical record reviews.

[3] CMS also contracts with Zone Program Integrity Contractors, known as ZPICs, that perform largely the same functions as UPICs. For ease of reference, this complaint uses UPIC to refer to either a UPIC or a ZPIC.

30. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, certain requirements, including complying with the Medicare statute and applicable regulations. 42 C.F.R. § 424.516(a)(1).

31. To participate in Medicare under Part B, "clinics, group practices, and other suppliers," such as individual practitioners and practices, must submit a Medicare Enrollment Application, Form CMS-855B. These entities must also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

32. Form CMS 855-B requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [this provider] . . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback statute [and the Stark law]). * * * I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf (last visited September 7, 2021).

33. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to the laws, regulations, and program instructions of the Medicare program." *Id.*

34. The National Provider Identifier (NPI) is a Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification Standard and unique

identification number for covered health care providers. The NPI was created to improve the efficiency and effectiveness of electronic transmission of health information. Covered health care providers, all health plans, and health care clearinghouses must use NPIs in their administrative and financial transactions. In addition, all providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

35. CMS requires a physician enrolled under Medicare Part B to list or disclose his or her NPI number when submitting claims if he or she ordered, rendered, supervised, or furnished covered reasonable and medically necessary Medicare items and/or services to beneficiaries. *See* CMS Manual, Pub. 100-04, Ch. 26.

36. Typically, physicians are compensated under Part B for covered items and services they provide to Medicare beneficiaries under CMS' Medicare Physician Fee Schedule (PFS). 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a covered item or service and must certify that the item or service was medically necessary for the Medicare beneficiary under section 1862(a)(1)(A) of the Act.

37. One of the factors that CMS uses to establish the PFS each year includes the practice expense. *See* 42 C.F.R. § 414.22(b). Practice expense is defined as "the portion of the resources used in furnishing the service that reflects the general categories of expenses . . . comprising practice expenses." 42 U.S.C. § 1395w-4(c)(1)(B).

38. CMS considers medical supplies to be part of the practice expense, "and payment for them is included in the practice expense portion of the payment to the

physician for the medical or surgical service to which they are incidental." 42. C.F.R. § 414.34(a)(1).

39. If a provider were to reuse a device incidental to a medical or surgical service for which the PFS calculated the cost of a new device for each service, the provider would receive more reimbursement than they were entitled to receive. Thus, providers who reuse medical supplies in this circumstance would violate the FCA because the provider is misrepresenting to Medicare the actual cost of performing the service.

40. Under Medicare Part B, providers are "paid 80 percent of allowed amount under the fee schedule amounts . . .[and] the patient is responsible for a coinsurance[4] amount equal to 20 percent of the fee schedule amounts . . ." CMS Manual, Pub. 100-01, Ch. 3, Sec. 20.3.

41. Medicare's determination as to the total payment for a covered service includes the coinsurance. If providers waive copayments, they are then receiving 100 percent of the cost of the service instead of only the 80 percent to which they are entitled. Thus, providers who routinely waive or reduce copayments violate the FCA because the provider is misrepresenting to Medicare the actual charge for the service. *See* CMS Manual, Pub. 100-04, Ch. 23, Sec. 80.8.1; *see also Publication of OIG Special Fraud Alerts*, 59 Fed. Reg. 65,372, 65,374-75 (Dec. 19, 1994).

42. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers submit a paper claim form known as the CMS 1500 form (CMS

[4] Coinsurance is also known as a copayment.

1500) or its electronic equivalent, known as the 837P format. Among the information the provider or supplier includes on a CMS 1500 or through the 837P format are certain five-digit codes, including Current Procedural Terminology (CPT) Codes and Healthcare Common Procedure Coding System (HCPCS) Level II codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source." Each code corresponds to a specific service.

43. When submitting claims to Medicare on the CMS 1500, providers certify, inter alia, that (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information on the claim form is "true, accurate, and complete"; (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws"; and (d) the claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment . . . ." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

44. When enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful[.]" https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited August 4, 2021).

45. Health care providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1), 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

46. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

47. At all times relevant to this Complaint, Dr. Jackson was an enrolled and participating Medicare provider.

48. At all times relevant to this Complaint, GCENT was an enrolled and participating Medicare provider.

49. Because it is not feasible for Medicare, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

50. Providers are generally only allowed to bill for services that they perform. Once a provider submits a CMS 1500, or the electronic equivalent, to Medicare, the claim is generally paid, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

51. During the relevant time period, Defendants billed Medicare under Part B for medical services including, but not limited to, balloon sinuplasty procedures, by submitting claims for reimbursement on the CMS 1500 or its electronic equivalent to Palmetto GBA.

III. The North Carolina Medicaid Program

52. The North Carolina Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq.* Medicaid is jointly funded by participating states and the federal government that provides health care benefits for certain groups, including the poor and disabled. Each state must have a single state agency to administer the Medicaid program. 42 U.S.C. § 1396a.

53. The North Carolina Division of Health Benefits (NCDHB) administers the Medicaid program in North Carolina and receives, processes, and pays claims for services under the Medicaid program. HHS periodically reimburses NCDHB for the federal share of all qualified Medicaid claims and ensures that the state complies with minimum standards in the administration of the program.

54. Providers bill Medicaid for services provided to Medicaid beneficiaries by submitting claim forms electronically to NCDHB through its fiscal agent. This fiscal agent was Computer Sciences Corporation, which later became CSRA Inc. Since April 2018, following an acquisition, CSRA has been known as GDIT.

55. A Medicaid provider must sign a Provider Agreement to participate in Medicaid. In so doing, the provider agrees to learn and adhere to Medicaid program policies, along with other federal and state regulations and Medicaid billing instructions.

The provider also acknowledges that Medicaid payment is conditioned upon compliance with Medicaid laws, regulations, and program instructions.

56. Medicaid requires compliance with their program policies, along with applicable statutes, regulations, and guidelines, as a precondition of government payment or reimbursement.

57. North Carolina state Medicaid providers may only submit claims for reimbursement that are medically necessary and accurately billed to Medicaid.

58. As with Medicare, a Medicaid provider must submit an equivalent version of the CMS 1500 for claims for reimbursement.

59. Medicaid requires compliance with the terms of the claim form as a precondition of government payment.

60. As a condition of payment, the Medicaid provider furnishes and certifies to certain information on the Medicaid claims form or submission, including the identity of the patient, the provider number, the procedure for which the provider is billing, the identity of the providers who are billing and rendering the service, and the value billed for the services provided.

61. NCDHB issues Medicaid policies, bulletins, and other materials to provide guidance to providers regarding which services are reimbursable by Medicaid and how to bill those services. *See* 42 C.F.R. § 431.18.

62. Some Medicare beneficiaries also have Medicaid benefits. When a patient has both Medicare and Medicaid coverage, they are referred to as "dually eligible."

Because Medicaid is the payor of last resort, Medicare is the primary insurer for dually eligible beneficiaries. Generally, claims submitted for dually eligible beneficiaries are paid pursuant to the Medicare policies applicable to the service provided/billed. Medicare pays approximately 80% of the claim value for dually eligible beneficiaries and Medicaid pays the remainder, minus a nominal co-payment if applicable. Claims for dually eligible beneficiaries may also be called "crossover claims."

63. At all times relevant to this Complaint, Dr. Jackson was an enrolled and participating Medicaid provider.

64. At all times relevant to this Complaint, GCENT was an enrolled and participating Medicaid provider.

65. Because it is not feasible for the Medicaid program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

66. During the relevant time period, Defendants billed Medicaid for medical services including, but not limited to, balloon sinuplasty procedures, by submitting claims for reimbursement to NCDHB through its fiscal agent.

IV. Adequacy of Medical Records

67. Under Medicare rules and policies, healthcare providers must contemporaneously create and maintain accurate medical records to support their claims for reimbursement. There must be sufficient documentation in the provider's records to

verify that the services performed were "reasonable and necessary." *See e.g.*, 42 U.S.C. § 1395l(e); CMS Medicare Learning Network (MLN) Matters Number: SE1022 ("Providers/suppliers should maintain a medical record for each Medicare beneficiary that is their patient. …[T]he medical records must be accurately written, promptly completed, accessible, properly filed and retained."); *see also* 42 U.S.C. § 1320c-5(a)(3).

68. Documentation is insufficient if Medicare cannot determine that some of the services were actually provided or were medically necessary. *See e.g.*, CMS MLN Fact Sheet: 909160, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CERTMedRecDoc-FactSheet-ICN909160.pdf (last visited August 9, 2021).

69. If the documentation in a medical record is absent or insufficient, there is no justification to bill Medicare or Medicaid for the services.

FACTUAL BACKROUND AND DEFENDANTS' FRAUDULENT SCHEME

I. Otolaryngology

70. Otolaryngology is a medical specialty focused on the care and treatment of the ear, nose, and throat (ENT). Otolaryngologists are physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, and throat, and related structures of the head and neck. They are commonly referred to as ENT physicians.

71. The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) is the leading professional organization for otolaryngologists.

72. AAO-HNS publishes clinical practice guidance and other studies to advise otolaryngologists on current standards of practice to help otolaryngologists "provide high-quality, evidence-informed, and equitable" care. American Academy of Otolaryngology—Head and Neck Surgery, *About Us*, https://www.entnet.org/about-us/ (last visited July 26, 2021).

73. When a patient presents with a sinus complaint, it is typical for an otolaryngologist to recommend medical therapy, such as nasal sprays or pills, as an initial step.

74. If medical therapy is ineffective, an otolaryngologist generally should perform a diagnostic nasal endoscopy (CPT code 31231) to visually inspect the sinuses and determine the next appropriate course of treatment, as explained in detail below.

75. At all times relevant to this complaint, the Defendants' fraudulent scheme involved the billing of procedures related to the diagnosing and treatment of disorders of the nose and sinuses, specifically CPT codes 31295 through 31298, as explained in detail below.

76. As described in detail below, the Defendants' billing of such codes was fraudulent because they billed for procedures Dr. Jackson never performed and/or that were not medically necessary. Moreover, the documentation in the medical records was absent or insufficient, such that it was impossible to determine if the services the Defendants billed to Medicare and Medicaid had actually been provided, and if so, whether such services were medically reasonable and necessary.

77. Each claim for payment that lacked sufficient supporting documentation in the medical record, which either was not performed or was not medically necessary, was a materially false and fraudulent claim for payment.

II. Dr. Jackson Knew of Medicare and Medicaid's Coverage Requirements Due to Her Audit History.

78. As set forth above, CMS contracts with private contractors called UPICs to perform program integrity functions for Medicare, including medical record reviews. UPICs are tasked with determining whether an item/service is correctly coded, that is, whether it meets all the coding guidelines listed in the CPT Manual, Coding Clinic for the International Classification of Disease, Coding Clinic for HCPCS, and any coding requirements listed in CMS Manuals or MAC articles. In certain situations, UPICs can up-code or down-code a claim (or items or services on a claim) and adjust the payment to the provider. CMS Manual, Pub. 100-08, Ch. 3, Sec. 3.6.2.4. UPICs are also tasked with evaluating and determining if there is evidence in the medical record that the service submitted was actually provided, and if so, if the service was medically reasonable and necessary. *Id*. Ch. 4, Sec. 4.3. Finally, UPICs are tasked with determining whether patterns and/or trends exist in a provider's medical record that may indicate potential fraud, waste, or abuse, or demonstrate potential patient harm. *Id*.

79. In 2001, a UPIC reviewed 300 claims from Dr. Jackson, from which it determined that Dr. Jackson's billing had a 31% error rate. This resulted in an overpayment of $34,658.00. The issues identified during this review included upcoding, billing for services not rendered, and billing for services not medically necessary.

80. In 2004, a UPIC reviewed 165 of Dr. Jackson's claims from which it determined a 27% error rate. This resulted in an overpayment of $3,425.13. The issues identified during this review included upcoding, billing for services without documentation, and billing for services without documentation of medical necessity.

81. In addition to requiring Dr. Jackson to return payment to Medicare after the 2004 audit, the UPIC also sent Dr. Jackson an education letter. The education letter outlined the specific issues identified, as well as reminders of Medicare policy. For example, the letter cited the Act and Part B Provider Manual to state, "[i]f the service . . . is not adequately documented in the medical record, the service is not billable to Medicare[,]" and "payment is only allowed for services that are considered to be medically and reasonably necessary in accordance with accepted medical standards."[5] The letter also reminded Dr. Jackson of the potential liability under the FCA, specifically citing 31 U.S.C. §§ 3729-30.

82. In 2016, a UPIC reviewed 20 of Dr. Jackson's claims and determined that 100% of the claims failed to meet Medicare coverage policies. This resulted in an overpayment of $31,035.26. The dates of service encompassed by the review were from July 21, 2015 through November 11, 2015, and some of the CPT codes at issue included 31295-31297. The issues identified were upcoding, billing for services not rendered, and billing for services that were not medically reasonable and necessary.

[5] The letter cited Sections 1156(a) and 1833(e) of the Act, which correspond to 42 U.S.C. § 1320c-5 and 1395l, respectively.

83. On June 22, 2016, the UPIC sent an education letter to Dr. Jackson outlining the findings of the audit and reminding her of Medicare policy and coverage requirements. In particular, the UPIC noted that "[t]he Operative Report in every single claim was cloned, word-for-word, beneficiary-to-beneficiary. It was not possible to determine operative processes and issues from these records." The letter further went on to cite the Act and the Medicare Benefit Policy to reiterate that "items and services which are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member are not covered . . ." *See also* 42 U.S.C. § 1395y; Soc. Sec. Act Sec. 1862(a)(1); CMS Manual, Pub. 100-02, Ch. 16, Sec. 20. Additionally, it cited Section 1156 of the Act in stating "that services or items . . . will be of a quality which meets professionally recognized standards of health care; and will be supported by evidence of medical necessity." *See also* 42 U.S.C. § 1320c-5. The UPIC emphasized that it "**will continue to monitor the provider's future Medicare claim submissions in order to verify adherence to this education.**" (emphasis in original).

84. In 2017, the MAC conducted a review of 36 of Dr. Jackson's claims and determined 100% of those claims were not reasonable and necessary. This resulted in an extrapolated overpayment of $1,704,223.52. The dates of service encompassed by the review were June 1, 2015 through December 31, 2016, and some of the CPT codes at issue included 31295-31297. When the MAC notified Dr. Jackson of the results on June 21, 2017, it advised Dr. Jackson that the issues identified for all 36 claims were that they were not medically necessary and that the documentation submitted lacked a date of service.

85. On January 8, 2018, a UPIC initiated an audit to review 30 claims for balloon sinuplasty services. The dates of service encompassed by the request were January 1, 2017 through December 31, 2017. Unlike prior audits, the UPIC found 0% of the claims should be denied.

86. Separately, on June 7, 2018 the MAC initiated an audit to review 27 claims for balloon sinuplasty services. Similar to the January 2018 audit, the MAC found very few issues with these claims. It ultimately only found a 4.5% error rate, which resulted in a $5,528.00 overpayment.

87. On June 16, 2021, Dr. Jackson was indicted in the Eastern District of North Carolina for falsifying medical records in connection with the two 2018 Medicare audits.

88. The indictment alleges that Dr. Jackson and GCENT employees altered existing documentation and created new documentation in support of the claims billed prior to submitting the supporting documentation to the UPIC and MAC.

89. Dr. Jackson was aware that prior audits found overpayments in part due to lack of documentation.

III. CPT Codes 31295-31298 and Balloon Sinuplasty

90. There are three sinus ostia on which balloon sinuplasty, also referred to as balloon dilation, can be performed: maxillary, frontal, and sphenoid.

91. CPT code 31295 is described as "nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa."

92. CPT code 31296 is described as "nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)."

93. CPT code 31297 is described as "nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)."

94. CPT code 31298 was created in 2018 and is described as "nasal/sinus endoscopy, surgical; with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia." This combines CPT codes 31296 and 31297.

95. Although Medicare has no specific coverage requirements for balloon sinuplasty (other than the overarching requirement that the procedure be medically reasonable and necessary), Medicaid enacted coverage requirements on February 1, 2018[6] which summarize the accepted standards of medical practice for the performance of balloon sinuplasty. NC Medicaid Clinical Coverage Policy No. 1A-42 (effective date February 1, 2018)[7](hereinafter "Policy No. 1A-42").

96. Before balloon sinuplasty is an indicated surgery, a patient must have the diagnosis of chronic rhinosinusitis (CRS)[8] lasting longer than 12 consecutive weeks and have failed medical therapy.

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[6] Prior to this date, Medicaid did not cover balloon sinuplasty at all. However, Defendants were still reimbursed from Medicaid prior to this date for any dually eligible beneficiaries, as Medicaid acted as a secondary payor in those instances.

[7] Policy No. 1A-42 was updated on March 15, 2019, but the information quoted herein did not change with the 2019 update.

[8] A diagnosis of recurrent acute rhinosinusitis is also an appropriate indicator for balloon dilation, but based on the billing records, Defendants did not diagnosis any patients with recurrent acute rhinosinusitis.

97. Policy No. 1A-42 defines medical therapy for CRS as "[a] minimum of two different oral antibiotics of two to four weeks duration for a beneficiary with chronic rhinosinusitis (culture-directed if possible)." *Id.* at 2.

98. During the relevant time period, Defendants' records have minimal evidence that patients failed medical therapy.

99. CRS can only be definitively diagnosed based on a patient's history of symptoms of sinusitis and physical evidence of a sinonasal abnormality (e.g., inflammation) or mucosal thickening obtained by nasal endoscopy and/or a CT scan of the sinuses.

100. In addition to a diagnosis of CRS, the otolaryngologist must confirm that the patient's nasal anatomy will allow for balloon sinuplasty.

101. For example, the presence of nasal polyps, a deviated septum, or other nasal blockages would be contraindications for balloon sinuplasty.

102. It has been the standard of care for otolaryngologists to perform a CT scan prior to any type of sinus surgery. Without a CT scan of the sinuses, an otolaryngologist cannot be sure which sinuses should be operated on, as the CT scan will give a fuller picture than an endoscopy about the sinuses, such as which sinuses are truly blocked, which have polyps, or if there are other anatomical issues of which the doctor needs to be aware.

103. Notably, AAO-HNS's *Clinical Consensus Statement: Balloon Dilation of the Sinuses* (hereinafter "*Consensus Statement*") had the most consensus on the statement, "[b]alloon dilation is not appropriate for patients who are without both sinonasal symptoms

and positive findings on CT." Jay F. Piccirillo, MD, et al., *Clinical Consensus Statement: Balloon Dilation of the Sinuses*, 158 OTOLARYNGOLOGY—HEAD AND NECK SURGERY, 203, 206 (Feb. 1, 2018). There was also extremely high consensus on the statement, "CT scanning of the sinuses is a requirement before balloon dilation can be performed." *Id.*

104. In addition, Policy No. 1A-42 requires a CT scan to be performed and have at least one of the following radiographic findings in the sinus to be dilated:

1. Bone remodeling and thickening;
2. Mucosal thickening greater than two millimeters;
3. Complete opacification; or
4. Obstruction of the ostiomeatal complex.

105. From 2012 through 2017, Defendants never billed Medicare or Medicaid for a diagnostic endoscopy. Defendants only first billed either Medicare or Medicaid for a diagnostic endoscopy in 2018.

106. During the entire relevant time period, Defendants never billed Medicare or Medicaid for a CT scan.

107. Upon information and belief, Defendants did not require patients receiving balloon sinuplasty to have a CT scan performed elsewhere before the procedure.

108. After a failure of medical therapy to resolve the sinus issues, a diagnosis of CRS with at least nasal endoscopy, and a CT scan to confirm the appropriate nasal anatomy and course of treatment (if one was not performed at the diagnosis stage), balloon sinuplasty may be an indicated course of treatment.

109. Logistically, the balloon sinuplasty procedure is typically scheduled for a date after the diagnosis and CT scan, as the physician needs time to review the CT and determine the appropriate sinuses for surgery.

110. During the relevant time period, Defendants[9] often billed Medicare and Medicaid for balloon sinuplasty surgery on the day of a patient's first office visit.

111. On the day of balloon sinuplasty surgery, the patient should first be given a decongestant and anesthetized, with either general or local anesthesia.

112. Without anesthesia, balloon sinuplasty is likely to be painful and extremely uncomfortable.

113. Once the anesthesia has set in, the otolaryngologist places a small, flexible balloon dilation device, often referred to as a balloon catheter, into the nose to reach the sinuses.

114. The balloon catheter is inflated once inside the sinus to push aside bones and gently restructure the nasal passage in an effort to improve sinus drainage or ventilation.

115. Because balloon sinuplasty permanently restructures bones, it is unlikely that a repeat procedure is necessary or effective.

116. If balloon sinuplasty does not relieve a patient's symptoms, another course of treatment may be needed.

[9] For Defendants' claims to Medicare and Medicaid, Defendants used GCENT as the billing provider NPI and Dr. Jackson as the rendering provider NPI. Because both GCENT and Dr. Jackson were involved in all claims to Medicare and Medicaid, the complaint uses "Defendants" collectively.

117. During the relevant time period, Defendants frequently billed Medicare and Medicaid for repeated balloon sinuplasty surgeries on the same patient over the course of months or years.

IV. Defendants' Scheme to Maximize Profit from Balloon Dilation

118. Dr. Jackson controlled all aspects of GCENT, including managing how patient visits were coded and billed and how charts were documented.

119. Dr. Jackson created or directed staff to create advertisements for a "sinus spa" or "sinus rinse." The sinus spa and/or sinus rinse were advertised as non-surgical solutions.

120. Upon information and belief, the "sinus spa" and "sinus rinse" created by Dr. Jackson were synonymous with what she was billing as balloon sinuplasty.

121. Dr. Jackson created pre-operation instructions for the "SinusSpa" describing the procedure. Among other things, the instructions stated:

> **What's it like:** This is an Office Deep Cleaning of Your Sinuses

122. A balloon sinuplasty is not a deep cleaning of sinuses that you may repeat as buildup occurs; it permanently restructures sinuses.

123. As discussed below, a sinus cleaning is more akin to sinus lavage (CPT codes 31000 and 31002).

124. In addition to the advertisements, Dr. Jackson required staff to meet performance goals, such as bringing in a certain dollar amount of billing. Dr. Jackson instructed staff to reach these goals by any means necessary, including recruiting family

members to come into the office for a sinus rinse. If a staff member did not meet these goals, Dr. Jackson would reduce the staff member's hours.

125. Another method Dr. Jackson used to maximize her profit was to reuse the balloon catheters on different patients.

126. The balloon catheters that Dr. Jackson used were largely manufactured by either Entellus (now Stryker) or Acclarent. Both devices are clearly labeled as single use only.

127. After noting that the device is intended for single use only, the Entellus instructions state "[d]o not resterilize and/or reuse, as it may result in compromised device performance and risk improper sterilization and cross-contamination."

128. Over time, the balloon catheter can become too flexible from overuse and can cause the physician to lack control where precision is needed.

129. The PFS also calculates the practice expense for balloon sinuplasty surgeries to include the cost of a new balloon catheter.

130. Defendants primarily used Entellus balloon catheters during the relevant period.

131. Defendants' total lifetime purchases of balloon catheters from Entellus were 36 devices.

132. In just 2015, Defendants billed Medicare for 401 balloon sinuplasty surgeries (CPT codes 31295 and 31296).

133. The national average for the Medicare population receiving *any* endoscopic procedure[10] is typically around 10%. By contrast, Dr. Jackson performed the balloon sinuplasty surgery on nearly 90% of her Medicare population during the relevant time period.

134. In North Carolina, Dr. Jackson was consistently the top biller for balloon sinuplasty during at least 2013 through 2017. In 2015, Dr. Jackson billed Medicare for 209 balloon sinuplasty surgeries for just CPT code 31296. The second highest biller in the state only billed Medicare for 37 procedures using CPT code 31296.

135. Similarly for Medicaid, Dr. Jackson was consistently the top biller. Between 2013 and 2017, Dr. Jackson billed Medicaid, including crossover claims, for 358 balloon sinuplasty surgeries for CPT code 31296. The second highest biller in the state only billed Medicaid for 15 procedures using CPT code 31296.

136. Dr. Jackson was also the top biller in the entire nation to Medicare for balloon sinuplasty from 2014 to 2017.

V. Defendants Billed Medicare and Medicaid for Balloon Sinuplasty Surgeries That Were Not Medically Reasonable or Necessary

137. As explained above, the diagnosis of CRS and consideration of balloon sinuplasty surgery should come only after failed medical therapy, visual inspection of the sinuses, and a CT scan.

[10] An endoscopic procedure is any procedure in which an endoscope is used to examine the interior of a hollow organ or body cavity. This includes many body parts besides the nasal cavities, such as the stomach, bladder, or bowels.

138. Dr. Jackson performed balloon sinuplasty on patients who had not failed medical therapy and/or received a CT scan.

139. Upon information and belief, Dr. Jackson did not refer her patients to another provider for a CT scan prior to performing a balloon sinuplasty procedure.

140. Dr. Jackson's medical records rarely support that a patient had failed medical therapy, either with Dr. Jackson overseeing the medical therapy or a different provider.

141. Dr. Jackson performed balloon sinuplasty on patients at their first office visit, which did not allow for accurate diagnosis and evaluation of anatomy for appropriateness of balloon sinuplasty.

142. For example, Medicare beneficiary B.E. visited Defendants on April 25, 2014, and Defendants billed Medicare for balloon sinuplasty (CPT codes 31295, 31296, and 31297). Medicare paid Defendants $4,258.66 for these false claims. April 25, 2014 was the first and only time beneficiary B.E. visited Defendants, and there was no evidence in the medical record of failed medical therapy, diagnostic endoscopy, or CT scan. Thus, Defendants billed Medicare for medically unreasonable and unnecessary services.

143. Similarly, Medicare beneficiary M.E. visited Defendants on October 25, 2013, and Defendants billed Medicare for balloon sinuplasty (CPT codes 31295 and 31296). Medicare paid Defendants $3,691.10 for these false claims. October 25, 2013 was the first time beneficiary M.E. visited Defendants, and there was no evidence in the medical record of failed medical therapy, diagnostic endoscopy, or CT scan. Thus, Defendants billed Medicare for medically unreasonable and unnecessary services.

144. Dual beneficiary J.W. visited Defendants as a new patient on August 31, 2017. On this date, Defendants billed Medicare (CPT codes 31295, 31296, and 31297), and Medicaid (CPT codes 31295 and 31296) for balloon sinuplasty. Medicare paid Defendants $5,510.21 and Medicaid paid Defendants $1,617.35 for these false claims. Notably, Defendants also billed Medicare and Medicaid for CPT code 99204, new patient outpatient visit for 45-59 minutes. August 31, 2017 was the first and only time dual beneficiary J.W. visited Defendants. Each of the balloon sinuplasty claims are fraudulent because they were medically unreasonable and unnecessary.

145. Defendants also repeatedly performed balloon sinuplasty on patients without regard to medical necessity, because it is rare that repeating the surgery will have therapeutic effects.

146. For example, Defendants billed Medicare for five separate balloon sinuplasty surgeries for beneficiary C.E. Notably, beneficiary C.E. received a balloon sinuplasty on her first two office visits with Defendants: July 22, 2014 and December 29, 2015. She then received three more balloon sinuplasty surgeries over the next two years. In addition to the lack of evidence of failed medical therapy, diagnostic endoscopy, or CT scan, there is also no evidence to substantiate the medical need for the repeated procedures. In all, Defendants billed Medicare and received $18,711.33 for the following purported balloon sinuplasty surgeries:

- July 22, 2014: CPT codes 31295, 31296, and 31297
- December 29, 2015: CPT codes 31295, 31296, and 31297
- July 25, 2016: CPT codes 31295, 31296, and 31297

- January 31, 2017: CPT codes 31295 and 31296
- October 10, 2017: CPT codes 31295 and 31296

Each of these claims was fraudulent because it was medically unreasonable and unnecessary.

147. Defendants also billed Medicare for five separate balloon sinuplasty surgeries for beneficiary K.P. Beneficiary K.P. received a balloon sinuplasty on August 12, 2014, the first office visit. In addition to the lack of evidence of failed medical therapy, diagnostic endoscopy, or CT scan, there is also no evidence to substantiate the medical need for the repeated procedures. In all, Defendants billed Medicare and received $19,091.76 for the following purported balloon sinuplasty surgeries:

- August 12, 2014: CPT codes 31295, 31296, and 31297
- May 26, 2015: CPT codes 31295, 31296, and 31297
- December 14, 2015: CPT codes 31295 and 31296
- July 19, 2016: CPT codes 31295 and 31296
- December 5, 2017: CPT codes 31295, 31296, and 31297

Each of these claims were fraudulent because they were medically unreasonable and unnecessary.

148. Defendants billed Medicare and Medicaid for five separate balloon sinuplasty surgeries for dual beneficiary R.I. Medicare paid Defendants $18,086.39 and Medicaid paid Defendants $13,971.44 for the following purported balloon sinuplasty surgeries:

- February 4, 2013: CPT codes 31295, 31296, and 31297

- April 17, 2014: CPT codes 31295, 31296, and 31297[11]
- May 18, 2015: CPT codes 31295, 31296, and 31297
- May 16, 2016: CPT codes 31295, 31296, and 31297[12]
- January 23, 2017: CPT codes 31295 and 31296

Each of these claims were fraudulent because they were medically unreasonable and unnecessary.

149. Defendants billed Medicare for eight and Medicaid for seven separate balloon sinuplasty surgeries for dual beneficiary J.G. Medicare paid Defendants $29,806.72 and Medicaid paid Defendants $8,482.71 for the following purported balloon sinuplasty surgeries:

- October 29, 2013: CPT codes 31295, 31296, and 31297 (Medicare only)
- October 14, 2014: CPT codes 31295, 31296, and 31297
- June 23, 2015: CPT codes 31295 and 31296
- January 12, 2016: CPT codes 31295, 31296, and 31297
- July 19, 2016: CPT codes 31295, 31296, and 31297
- January 10, 2017: CPT codes 31295, 31296, and 31297
- October 3, 2017: CPT codes 31295 and 31296
- November 19, 2018: CPT codes 31295 and 31298 (31298 only billed to Medicaid)

Each of these claims were fraudulent because they were medically unreasonable and unnecessary.

[11] Medicaid shows the date of service as April 16, 2014, but only Medicare reimbursed Defendants for this date of service.

[12] It appears Medicare originally reimbursed Defendants for this service but have since made an overpayment adjustment such that Defendants received $0 for balloon sinuplasty surgeries on this date. The overall calculation of how much Defendants have been paid reflect only monies paid by Medicare or Medicaid.

150. In addition to the objective billing evidence (i.e., lack of diagnostic billing and/or repeat procedures), the medical records lack sufficient information to determine whether the balloon sinuplasty surgeries performed were medically necessary and reasonable.

VI. Defendants Did Not Render Balloon Sinuplasty Services as Billed to Medicare and Medicaid

151. Several of Defendants' patients did not recall the term "balloon sinuplasty" or "balloon dilation." Moreover, patients described procedures consistent with a sinus lavage by cannulation (CPT codes 31000 and 31002)—for which Defendants also frequently billed—rather than balloon sinuplasty. Upon information and belief, this is because Defendants did not actually perform balloon sinuplasty on these and other patients.

152. Sinus lavage is the irrigation and drainage of the sinus done by inserting a tube into a patient's sinus and using a rinse to clear the sinus.

153. Defendants billed Medicare for balloon sinuplasty of beneficiary K.P. on five separate occasions (as outlined in paragraph 147). K.P. reported that Dr. Jackson rinsed out her sinus multiple times, but she denied ever receiving a balloon sinuplasty. Beneficiary K.P. also reported that she felt the sinus rinses were unnecessary and not helping her sinus issues. Medicare paid Defendants $19,091.76 for these services not rendered.

154. Defendants billed Medicare and Medicaid for balloon sinuplasty (CPT codes 31295, 31296, and 31297) for dual beneficiary P.L. on October 25, 2017. This was beneficiary P.L.'s first and only visit to Defendants. Beneficiary P.L. reported that she never received a balloon sinuplasty, nor did she have any sinus issues when she visited

Defendants' office. Medicare paid Defendants $6,720.89 and Medicaid paid Defendants $1,470.95 for these services not rendered.

155. Defendants billed Medicare for balloon sinuplasty (CPT codes 31295 and 31298) for beneficiary C.L. on February 26, 2018. Beneficiary C.L. denied receiving the procedure and stated that he did not have any work done related to his sinuses. Medicare paid Defendants $6,201.34 for these services not rendered.

156. Defendants' medical records also do not support that Defendants performed balloon sinuplasty surgeries.

157. In nearly every patient file, there is a template operative report that lists the procedures performed, including balloon sinuplasty on all sinuses, regardless of whether Defendants billed Medicare for all sinuses. The report then describes how the procedure was performed and states that "the patient tolerated the procedure well." The report is not altered from patient to patient. The reports also frequently have no information filled out, such as the patient's name, date of the procedure, or Dr. Jackson's signature.

158. Notably, on June 16, 2021, Dr. Jackson was indicted for, among other things, falsifying medical records in connection with Medicare audits.

159. Defendants also waived or significantly reduced copayments for the procedure on multiple occasions.

160. Under Medicare Part B, once a beneficiary has paid their annual deductible,[13] the beneficiary is responsible for a 20 percent copayment.

161. Because the rates for balloon sinuplasty are high, copayments for the procedure would be in the hundreds to thousands depending on the number of CPT codes billed.

162. Defendants waived or significantly reduced the copayments to conceal the expensive nature of the procedure for which Defendants billed.

163. For example, Defendants billed Medicare for balloon sinuplasty (CPT codes 31295, 31296, and 31297) on October 30, 2017 for beneficiary H.W. The balloon sinuplasty was performed on the first day that H.W. went to visit Defendants. In addition, beneficiary H.W. reported that she went to Defendants for an ear infection and did not recall discussing balloon sinuplasty or any balloon procedures. Beneficiary H.W.'s medical record contains an unsigned template operative report, as described above. Beneficiary H.W. owed a $1400 copayment, but Defendants reduced this amount to $50. Medicare paid Defendants $5,650.81 for these services not rendered.

164. As indicated above with the template operative reports, the Defendants' medical records are so inadequate that it is not possible to determine whether balloon sinuplasty was actually performed.

[13] Although the annual deductible generally increases from year to year, for reference, the annual deductible in 2020 was $198.00.

FIRST CAUSE OF ACTION
Against GCENT and Jackson

False Claims Act: Presenting and Causing False Claims – Medically Unnecessary and Unreasonable Balloon Sinuplasty Furnished by GCENT and Jackson or Services Not Rendered by GCENT and Jackson (31 U.S.C. § 3729(a)(1)(A))

165. The Governments re-allege and incorporate by reference all Paragraphs of this Complaint set out above as if fully set forth here.

166. During the relevant time period, GCENT and Dr. Jackson knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to Medicare and Medicaid for medically unnecessary and unreasonable balloon sinuplasty procedures.

167. During the relevant time period, GCENT and Dr. Jackson knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to Medicare and Medicaid for balloon sinuplasty procedures that were not performed.

168. Defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

169. The Governments sustained damages because of this wrongful conduct.

SECOND CAUSE OF ACTION
Against GCENT and Jackson

False Claims Act: False Statements Material to False Claims – Medically Unnecessary and Unreasonable Balloon Dilation Furnished by GCENT and Jackson or Services Not Rendered by GCENT and Jackson (31 U.S.C. § 3729(a)(1)(B))

170. The Governments re-allege and incorporate by reference all Paragraphs of this Complaint set out above as if fully set forth here.

171. During the relevant time period, GCENT and Dr. Jackson knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the Defendants' statements and actions.

172. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for balloon sinuplasty furnished by Dr. Jackson and GCENT that were billed to Medicare and Medicaid were medically necessary and reasonable, when, in fact, that balloon sinuplasty was medically unnecessary and unreasonable.

173. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for balloon sinuplasty furnished by Dr. Jackson and GCENT that were billed to Medicare and Medicaid were performed, when, in fact, that balloon sinuplasty was not performed for the beneficiary.

174. Defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

175. The United States sustained damages because of this wrongful conduct.

THIRD CAUSE OF ACTION
Against GCENT and Jackson

North Carolina False Claims Act: Presenting and Causing False Claims – Medically Unnecessary and Unreasonable Balloon Dilation Furnished by GCENT and Jackson or Services Not Rendered by GCENT and Jackson (N.C.G.S. §1-605, *et seq.)*

176. The Governments re-allege and incorporate by reference all Paragraphs of this Complaint set out above as if fully set forth here.

177. During the relevant time period, GCENT and Dr. Jackson knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to Medicaid for medically unnecessary and unreasonable balloon sinuplasty.

178. During the relevant time period, GCENT and Dr. Jackson knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to Medicaid for balloon sinuplasty procedures that were not performed.

179. Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment to a recipient of Medicaid funds to be spent or used on the State of North Carolina's behalf and to advance healthcare programs under the Medicaid program in violation of N.C.G.S. §1-607(a)(1).

180. Through the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to false or fraudulent claims for payment or approval to a recipient of Medicaid funds to be spent or used on the Government's behalf and to advance healthcare programs, in violation of N.C.G.S. §1-607(a)(2).

181. Through the acts described above, Defendants knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money or property to the Government. Due to Defendants' obligations to return moneys unlawfully and/or fraudulently obtained by Defendants, Defendants are liable under N.C.G.S. §1-607(a)(7).

182. Due to Defendants' presentation of false or fraudulent claims, Defendants were reimbursed with Medicaid funds for services that Defendants otherwise would not have received.

183. By reason of Defendants' false or fraudulent claims, the State of North Carolina suffered damages and therefore is entitled to treble damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

184. By reason of Defendants making, using, or causing to be made or used a false record or statement material to false or fraudulent claims, the State of North Carolina suffered damages and therefore is entitled to treble damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

185. Defendants are liable to the State of North Carolina for the costs of this civil action under N.C.G.S. §1-607(a).

FOURTH CAUSE OF ACTION
Against GCENT

Payment by Mistake – Medically Unreasonable and Unnecessary Services or Services Not Rendered

186. The Governments re-allege and incorporate by reference all Paragraphs of this Complaint set out above as if fully set forth here.

187. This is a claim for the recovery of monies paid by the Governments during the relevant time period to Defendant GCENT as a result of mistaken understandings of fact.

188. The Governments paid GCENT for balloon sinuplasty that did not comply with the requirements of Medicare and Medicaid. The Governments made these payments without knowledge of material facts and under the mistaken belief that GCENT was entitled to receive payment for such claims when it was not. The Governments' mistaken beliefs were material to its decision to pay GCENT for such claims. Accordingly, GCENT is liable to make restitution to the Governments of the amounts of the payments made in error to GCENT by the Governments.

FIFTH CAUSE OF ACTION
Against GCENT and Jackson

Unjust Enrichment

189. The Governments re-allege and incorporate by reference all Paragraphs of this Complaint set out above as if fully set forth here.

190. This is a claim for the recovery of monies by which Defendants have been unjustly enriched during the relevant time period at the expense of the Governments.

191. By directly or indirectly obtaining government funds to which they were not entitled, Defendants each were unjustly enriched, and are liable to account for and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the Governments.

SIXTH CAUSE OF ACTION
Against GCENT and Jackson

Common Law Fraud

192. The Governments re-allege and incorporate by reference all Paragraphs of this Complaint set out above as if fully set forth here.

193. This is a claim at common law for fraud and deceit.

194. The false statements made by Defendants as described above were misrepresentations of material facts.

195. Defendants made these misrepresentations of material facts with knowledge of their falsity and/or with reckless disregard for their truth.

196. Defendants made these misrepresentations of material facts intending that the Governments would rely on their accuracy in paying the claims submitted.

197. The Governments justifiably relied upon Defendants' misrepresentations in making payments to Defendants.

198. Through the acts described above, Defendants have perpetuated a fraud and deceit upon the Governments and, as a result, the Governments have suffered damages for the above-referenced fraud.

PRAYER FOR RELIEF

The Governments demand and pray that judgment be entered in their favor against Defendants as follows:

A. On Counts I and II under the False Claims Act, for the amount of damages during the relevant time period, trebled as required by law, plus costs of investigation

and prosecution, and such civil penalties for each false claim as are authorized by law, together with such further relief as may be just and proper.

B. On Count III under the North Carolina False Claims Act, for the amount of the State of North Carolina's damages during the relevant time period, trebled as required by law, plus costs of investigation and prosecution, and such civil penalties for each false claim as are authorized by law, together with such further relief as may be just and proper.

C. On Count IV for payment by mistake, against Defendant GCENT, for the damages sustained and/or amounts by which GCENT was paid by mistake or by which GCENT retained illegally obtained monies during the relevant time period, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

D. On Count V for unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies during the relevant time period, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

E. On Count VI for common law fraud, for damages sustained and/or amounts by which Defendants perpetrated fraud against the Governments, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

F. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The Governments demand a jury trial in this case on all issues so triable.

Dated: November 18, 2021

Respectfully submitted,

FOR THE UNITED STATES:

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CERTIFICATE OF SERVICE

I hereby certify that on November 18, 2021, the foregoing was served by electronic means pursuant to Local Rule 5.3(c)(3) upon the following:

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Rule 4 service of this Complaint and Summons upon Defendants will follow.

/s/ Rebecca Mayer
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